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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,426	04/09/2004	Paul Alan Jass	CC-0312-04	1234

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EXAMINER

VALENROD, YEVGENY

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,426

Applicant(s)

JASS ET AL.

Examiner

Yevgeny Valenrod

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-13 is/are rejected.
- 7) ☒ Claim(s) 5-7, 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Claims 1-15 are pending,
- Rejection of claims 5-7 under 35 USC 112 2nd paragraph is withdrawn in view of - applicants' amendment.
- Rejection of claims 11-15 under 35 USC 1st paragraph is withdrawn in view of applicants' amendment.
- Rejection of claims 1-4 and 8-10 is maintained and made final. Text of the rejection and examiners reply to applicants' remarks appear below.
- Claims 11-13 are newly rejected see below. The rejection was necessitated by the applicants amendment and is made final.

Claim Rejections - 35 USC § 103

1. Claims 1-4, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jass (US 6,323,359) in view of Wang (US 3,485,843).

The inventive step of the instant application is the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound as a solvent for the deprotonation of a probucol compound.

Scope of prior art

2. Jass teaches preparation of water-soluble derivatives of probucol. In Column 3, lines 21-30 the method of deprotonating a probucol compound to form an ammonium or a metal salt is described. The substitutions in the probucol compound are described in column 2, lines 20-35 and their scope is largely in accordance with the substitution

Art Unit: 1621

options of the probucol compounds in the instant application, difference being that R1 and R2 can have up to 8 carbons in the reference and only up to 6 in the application and R3, R4, R5, R6 can have up to 4 carbons in the reference and up to 6 in the application. In example 1 in column 4, lines 50-60 the process of deprotonation is described in detail. The solvent is added at 20-25°C (line 53), however on line 58 Jas says that there is a temperature drop from 35°C to 22°C. This indicates that the reaction was proceeding at 35°C (limitations of claims 8-10).

Ascertaining the difference between prior art and the instant claims

3. Jass teaches the process of deprotonating probucol compounds and subsequently reacting the obtained salt with electrophiles. However, Jess only teaches the use of THF or acrylonitrile as a solvent for deprotonation and does not teach the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound for the same purpose.

Secondary reference

4. Wang teaches preparation of ammonium salts of probucol compounds from their protonated derivatives (column 1, lines 19-33) by treating the protonated probucol derivative with piperazine in acetone (column 1 lines 48-52). Wang is able to recover the formed salt by cooling the reaction mixture and allowing the product to precipitate (column 2 lines 8-10).

Motivation to combine

5. Ammonium salts of probucol can be conveniently separated from the reaction mixture by cooling the mixture in acetone and precipitating the desired product (Wang,

Art Unit: 1621

Column 2, lines 8-10). One wishing to have the option of easily separating the ammonium salt from the reaction mixture and then using a predetermined amount of that salt for further reaction with electrophiles (as taught by Jass) would be motivated to use acetone as a solvent for the process of deprotonating probucol compounds (as taught by Wang). One of ordinary skill in the art would therefore be motivated to combine with reasonable expectation of success Wang's process of forming the ammonium salt in acetone and Jasses process of making probucol derivatives. The expected result would be production of probucol derivatives where acetone is used in the deprotonation step (step 1 according to the instant invention).

Reply to Applicants Remarks

6. In Traversal of the above rejection, Applicant refers to the submitted documents, which indicate that the instant invention and US 6,323,359 were commonly owned by Cambrex Charles City, Inc. Applicant cites MPEP 706.02(1)(2). MPEP 706.02(1)(2) states:

"In order to be disqualified as prior art under **35 U.S.C. 103(c)**, the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention was made." MPEP 706.02(1)(2)

The cited paragraph refers to rejections made under 35 U.S.C. 103(c). Had the rejection been made based on the filing date of US 6,323,359, showing common

ownership would have overcome the rejection. However, in the instant case, the issue date is used for the rejection purposes and the rejection is made under 35 USC 103(a) not 103 (c). Rejection of claims 1-4 and 8-10 is maintained and is made final.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claims 1-4, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jass (US 6,323,359) in view of Wang (US 3,485,843).

The inventive step of the instant application is the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound as a solvent for the deprotonation of a probucol compound.

Scope of prior art

8. Jass teaches preparation of water-soluble derivatives of probucol. In Column 3, lines 21-30 the method of deprotonating a probucol compound to form an ammonium or a metal salt is described. The substitutions in the probucol compound are described in column 2, lines 20-35 and their scope is largely in accordance with the substitution options of the probucol compounds in the instant application, difference being that R1 and R2 can have up to 8 carbons in the reference and only up to 6 in the application and R3, R4, R5, R6 can have up to 4 carbons in the reference and up to 6 in the application. In example 1 in column 4, lines 50-60 the process of deprotonation is described in detail. Jeff also teaches a treating a mixture that comprises the product of

Art Unit: 1621

step (2) with 40 mL. 1.3N HCl and diluting it with 200 mL of heptanes (Column 5, lines 33-37).

Ascertaining the difference between prior art and the instant claims

9. Jass teaches the process of deprotonating probucol compounds and subsequently reacting the obtained salt with electrophiles. However, Jess only teaches the use of THF or acrylonitrile as a solvent for deprotonation and does not teach the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound for the same purpose. Although Jass teaches treating the mixture of step (2) with HCl, there is no reference to pH being less than 7.

Motivation to combine

10. Ammonium salts of probucol can be conveniently separated from the reaction mixture by cooling the mixture in acetone and precipitating the desired product (Wang, Column 2, lines 8-10). One wishing to have the option of easily separating the ammonium salt from the reaction mixture and then using a predetermined amount of that salt for further reaction with electrophiles (as taught by Jass) would be motivated to use acetone as a solvent for the process of deprotonating probucol compounds (as taught by Wang). One of ordinary skill in the art would therefore be motivated to combine with reasonable expectation of success Wang's process of forming the ammonium salt in acetone and Jasses process of making probucol derivatives. The expected result would be production of probucol derivatives where acetone is used in the deprotonation step (step 1 according to the instant invention).

Although the pH of the Solution obtained by Jass is not disclosed, it obvious a person of ordinary skill in the art that while washing with 1.3 M HCl the pH of the mixture is less then 7.

New rejection of claims 11-13 was necessitated by the applicants' amendment and is therefore made final.

Claim Objections / Allowable subject matter

Claims 5-7 and 14-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. For claims 5-7, prior art search failed to uncover references that disclose or suggest the probucol to solvent ratios which correspond to the ratios claimed in the instant application. For claims 14-15, although treatment with acid and heptanes is taught in US 6,323,359, there is no suggestion for admixing heptanes at elevated temperatures.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

- Claims 1-15 are pending
- Claims 1-4, 8-13 are rejected
- Claims 5-7 and 14-15 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

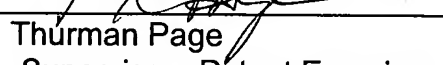
Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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